

WHAT IS CLAIMED IS:

1. A composition for modulating an immune response to a target antigen, comprising a lectin-interactive agent and an immune-modulating agent selected from the group consisting of an antigen that corresponds to at least a portion of the target antigen, an antigen-binding molecule that is immuno-interactive with the target antigen and an immune-modulating cell that modulates an immune response to the target antigen.
2. A composition according to claim 1, wherein lectin is expressed by an organism.
3. A composition according to claim 2, wherein the organism is selected from the group consisting of bacteria, entamoeba, protozoans, insects, gastropods, plants and animals.
4. A composition according to claim 2, wherein the organism is an animal and the lectin is selected from the group consisting of calnexin, M-type lectins, L-lectins, P-lectins, C-lectins, galactoside-binding lectins, I-type lectins and R-lectins.
5. A composition according to claim 1, wherein lectin is expressed by a cancer or tumour.
6. A composition according to claim 5, wherein the lectin is a galectin.
7. A composition according to claim 6, wherein the galectin is selected from the group consisting of galectin-1, galectin-3 and galectin-9.
8. A composition according to claim 1, wherein the lectin-interactive agent is a carbohydrate or carbohydrate-containing molecule selected from the group consisting of monosaccharides, disaccharides larger saccharides, synthetic carbohydrates, glycopeptides, N-acetyllactosamine derivatives, modified polysaccharides, starburst dendrimers and glycopolymers.
9. A composition according to claim 8, wherein the disaccharides are selected from the group consisting of lactose, lactulose, lactosucrose, methyl β -lactoside, D-galactose, 4-O- β -D-galactopyranosyl-D-mannopyranoside, 3-O- β -D-galactopyranosyl-D-arabinose, 2'-O-methyl lactose, lacto-N-biose, N-acetyllactosamine, thiodigalactopyranoside, D-lactitol monohydrate, lactobionic acid, benzyl 4-O- β -D-galactopyranosyl- β -D-glucopyranoside, methyl 4-O- β -D-galactopyranosyl- β -D-glucopyranoside, 2-methyl- β -D-galactose (1 \rightarrow 4) D-glucose, carbomethoxyethylthioethyl 2 acetamido-2-deoxy-4-O- β D galactopyranosyl- β -D-glucopyranoside, 4-nitrophenyl 2-acetamido-2-deoxy-3-O- β -D galactopyranosyl- β -D-glucopyranoside and N-propyl- β -lactoside.
10. A composition according to claim 8, wherein the larger saccharides are selected from the group consisting of polylactosamine, polylactosamine-carrying glycopeptides and modified plant pectin polysaccharide.
11. A composition according to claim 8, wherein the synthetic carbohydrate thiodigalactoside.
12. A composition according to claim 8, wherein the glycopeptides comprise lactose or galactose.

13. A composition according to claim 8, wherein the carbohydrate or carbohydrate-containing molecule is not metabolised in the host to which the composition is administered. A composition according to claim 7, wherein the carbohydrate or carbohydrate-containing molecule is selected from the group consisting of lactulose, methyl 2-acetamido-2-deoxy-4-O-(3-[3-carboxypropanamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[{Z}-3-carboxy-propenamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-benzamido-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[2-carboxybenzamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[4-methoxy-2,3,5,6-tetrafluorobenzamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[2-carboxy-3,4,5,6-tetrafluoro-benzamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-methane-sulfonamido-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[4-nitrobenzenesulfonamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-phenylaminocarbonylamino-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(2-aminoacetamido-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[{2S}-2-amino-3-carboxy-propanamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside.

14. A composition according to claim 8, wherein the carbohydrate or carbohydrate-containing molecule is lactulose or synthetic or semi-synthetic analogue thereof.

15. A composition according to claim 8, wherein the carbohydrate or carbohydrate-containing molecule is selected from the group consisting of methyl 2-acetamido-2-deoxy-4-O-(3-[3-carboxypropanamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[{Z}-3-carboxypropenamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-benzamido-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[2-carboxybenzamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[4-methoxy-2,3,5,6-tetrafluorobenzamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-(2-carboxy-3,4,5,6-tetrafluorobenzamido)-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-methane-sulfonamido-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[4-nitrobenzenesulfonamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-phenylaminocarbonylamino-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(2-aminoacetamido-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[{2S}-2-amino-3-carboxy-propanamido]-3-deoxy-β-D-galactopyranosyl)-β-D-glucopyranoside. In some

embodiments of this type, the carbohydrate is methyl 2-acetamido-2-deoxy-4-O-(3-benzamido-3-deoxy- β -D-galactopyranosyl)- β -D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[2-carboxy-benzamido]-3-deoxy- β -D-galactopyranosyl)- β -D-glucopyranoside, methyl 2-acetamido-2-deoxy-4-O-(3-[4-methoxy-2,3,5,6-tetrafluorobenzamido]-3-deoxy- β -D-galactopyranosyl)- β -D-glucopyranoside, or methyl 2-acetamido-2-deoxy-4-O-(3-[2-carboxy-3,4,5,6-tetrafluorobenzamido]-3-deoxy- β -D-galactopyranosyl)-D-glucopyranoside.

16. A composition according to claim 1, wherein the lectin-interactive agent has a binding affinity for the lectin in the range from about 10^{-3} to about 10^{-9} M.

17. A composition according to claim 1, comprising at least two lectin-interactive agents.

10 18. A composition according to claim 1, comprising at least two lectin- carbohydrate or carbohydrate-containing molecules.

19. A composition according to claim 18, wherein one of the carbohydrates or carbohydrate-containing molecules is soluble so that it can diffuse readily through the body of an animal and wherein the other is a larger saccharide that is partially soluble so as to limit its diffusion from the site of delivery to the animal.

20. A composition according to claim 1, wherein the antigen is selected from the group consisting of a peptide, a polypeptide, a nucleic acid molecule from which any of these is expressible, a whole cell, a pathogen and an antigen-presented by an antigen-presenting cell.

20 21. A composition according to claim 1, wherein the target antigen is selected from the group consisting of simple intermediary metabolites, sugars, lipids, hormones, macromolecules, phospholipids, nucleic acids, polypeptides and peptides.

22. A composition according to claim 1, wherein the target antigen is selected from the group consisting of endogenous antigens produced by a host and exogenous antigens that are foreign to the host.

25 23. A composition according to claim 22, wherein the endogenous antigens are selected from the group consisting of self-antigens that are targets of autoimmune responses and cancer or tumour antigens.

24. A composition according to claim 1, wherein the target antigen is expressed by a cancer or a pathogenic organism.

30 25. A composition according to claim 24, wherein the composition is adapted to stimulate or otherwise enhance an immune response to the target antigen.

26. A composition according to claim 1, wherein the target antigen is associated with an unwanted immune response.

35 27. A composition according to claim 26, wherein the unwanted immune response is selected from the group consisting of transplant rejection, graft *versus* host disease, allergies, parasitic diseases, inflammatory diseases and autoimmune diseases.

28. A composition according to claim 27, wherein the composition is adapted to induce a tolerogenic response to the target antigen, wherein the response is selected from the group consisting of an anergic response and the suppression of a future or existing immune response.

29. A composition according to claim 1, wherein the immune-modulating cell is an antigen-presenting cell that stimulates an immune response.

30. A composition according to claim 1, wherein the immune-modulating cell is an antigen-presenting cell that induces a tolerogenic response.

31. A composition according to claim 29, wherein the antigen-presenting cell is a cell to which an immune response is required and which has been optionally modified to enhance its antigen-presenting functions.

32. A composition according to claim 29, wherein the antigen-presenting cell is modified by culturing the cell in the presence of a type II interferon (IFN) and optionally at least one type I IFN for a time and under conditions sufficient to enhance the antigen-presenting function of the cell and washing the cell to remove the IFN.

33. A composition according to claim 29, wherein the antigen-presenting cell is modified by introducing a construct into the cell from which one or more IFNs selected from a type II IFN and a type I IFN are expressible.

34. A composition according to claim 29, wherein the antigen-presenting cell is an allogeneic antigen-presenting cell or cell line that shares major and/or minor histocompatibility antigens to a recipient of the composition.

35. A composition according to claim 1, wherein the immune-modulating cell is an immune effector cell selected from the group consisting of T lymphocytes and B lymphocytes.

36. A composition according to claim 35, wherein the T lymphocytes are selected from the group consisting of cytolytic T lymphocytes helper T lymphocytes and T regulatory cells.

37. A composition according to claim 1, wherein the antigen-binding molecule binds to or otherwise interacts with the target antigen so as to reduce its level or functional activity.

38. A composition according to claim 1, further comprising one or more immunoregulatory molecules selected from the group consisting of co-stimulatory molecules, cytokines and co-inhibitory molecules.

39. A composition according to claim 38, wherein the co-stimulatory molecules are selected from the group consisting of B7-1, B7-2, B7-3, ICAM-1 and ICAM-2.

40. A composition according to claim 38, wherein the cytokines are selected from the group consisting of interferons, granulocyte/macrophage-colony stimulating factor (GM-CSF), interleukin-10 and tumour necrosis factor α (TNF- α).

41. A composition according to claim 38, wherein the co-inhibitory molecules are selected from the group consisting of OX-2 and programmed death-1 ligand (PD-1L).

42. A composition according to claim 38, wherein the immunoregulatory molecule(s) is/are provided in soluble form.

43. A composition according to claim 38, wherein the immunoregulatory molecule(s) is/are produced intracellularly from an expression construct or vector.

44. A composition according to claim 1, further comprising an adjuvant.

45. A composition according to claim 1, further comprising a pharmaceutically acceptable
5 carrier.

46. A method for modulating an immune response to a target antigen in a subject, comprising administering to the subject a composition comprising a lectin-interactive agent and an immune-modulating agent selected from the group consisting of an antigen that corresponds to at least a portion of the target antigen, an antigen-binding molecule that is immuno-interactive with
10 the target antigen and an immune-modulating cell that modulates an immune response to the target antigen.

47. A method according to claim 46, wherein the lectin-interactive agent and the immune-modulating agent is administered sequentially, separately or simultaneously.

48. A method according to claim 46, which is used for the treatment or prophylaxis of a
15 disease or condition associated with the presence or aberrant expression of the target antigen in a subject.

49. A method according to claim 48, wherein the disease or condition is treated or prevented by using a composition that stimulates or otherwise enhances an immune response to the target antigen.

20 50. A method according to claim 48, wherein the disease or condition is selected from a pathogenic infection, a disease characterised by immunodeficiency and a cancer or tumour.

51. A method according to claim 48, wherein the disease or condition is treated or prevented by using a composition that elicits a tolerogenic response to the target antigen.

52. A method according to claim 48, wherein the disease or condition is selected from
25 transplant rejection, graft *versus* host disease, allergies, parasitic diseases, inflammatory diseases and autoimmune diseases.

53. Use of a lectin-interactive agent and an immune-modulating agent in the manufacture of a medicament for modulating an immune response to a target antigen, wherein the immune-modulating agent is selected from group consisting of an antigen that corresponds to at least a
30 portion of the target antigen, an antigen-binding molecule that is immuno-interactive with the target antigen and an immune-modulating cell that modulates an immune response to the target antigen.

54. Use of a lectin-interactive agent and an immune-modulating agent in the manufacture of a medicament for treating or preventing a disease or condition associated with the presence or
35 aberrant expression of a target antigen, wherein the immune-modulating agent is selected from group consisting of an antigen that corresponds to at least a portion of the target antigen, an antigen-binding molecule that is immuno-interactive with the target antigen and an immune-modulating cell that modulates an immune response to the target antigen.

55. A method for identifying a lectin-interactive agent, comprising (a) culturing a first sample of a population of immune effector cells in the presence of a first sample of a lectin-expressing cell or pathogen; (b) culturing a second sample of the population in the presence of a second sample of the lectin-expressing cell or pathogen and a candidate agent suspected of having
5 lectin-interaction activity, and (c) quantifying the immune effector cells in the first and second samples, respectively, whereby an increase in the number of immune effector cells in the second sample as compared to the first sample indicates that the candidate agent is a lectin-interactive agent.

56. A method according to claim 55, wherein the population of immune effector cells is
10 selected from populations of white blood cells.

57. A method according to claim 55, wherein the population of immune effector cells is homogenous or heterogeneous.

58. A method according to claim 55, wherein the population of immune effector cells is selected from the group consisting of whole blood, fresh blood and fractions of any one of these.

59. A method according to claim 58, wherein the fractions are selected from the group
15 consisting of peripheral blood mononuclear cells, buffy coat fractions of whole blood, packed red cells, irradiated blood, dendritic cells, monocytes, macrophages, neutrophils, lymphocytes, natural killer cells and natural killer T cells.

60. A method according to claim 55, wherein the lectin-expressing cell is a tumour cell.

61. A method according to claim 60, wherein the tumour cell is selected from the group
20 consisting of a melanoma cell and a breast cancer cell.

62. A method for assaying the activity of a lectin-interactive agent, comprising (a) culturing a first sample of a population of immune effector cells in the presence of a first sample of a lectin-expressing cell or pathogen; (b) culturing a second sample of the population in the presence
25 of a second sample of the lectin-expressing cell or pathogen and a lectin-interactive agent, and (c) quantifying the immune effector cells in the first and second samples, respectively.

63. A method according to claim 62, wherein the difference in the number of immune effector cells between the second sample and the first sample is indicative of the lectin-interactive activity.

64. A method according to claim 62, wherein the immune effector cells are quantified
30 using a cytolytic T lymphocyte assay.